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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,176	11/24/2003	Tariq M. Rana	UMY-059	3047

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EXAMINER	
CHONG, KIMBERLY	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 05/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/722,176	RANA, TARIQ M.	
	Examiner	Art Unit	
	Kimberly Chong	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-16* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3, drawn to a method for delivering a siRNA or engineered RNA to a cell wherein the method comprises conjugating a Tat delivery peptide (SEQ ID NO: 12) to a siRNA or engineered RNA, classifiable in class 435, subclass 375.

II. Claims 1 and 4, drawn to a method for delivering an siRNA or engineered RNA to a cell wherein the method comprises conjugating the delivery peptide hox to a siRNA or engineered RNA, classifiable in class 435, subclass 375

III. Claims 1 and 5, drawn to a method for delivering an siRNA or engineered RNA to a cell wherein the method comprises conjugating the delivery peptide MTS to an siRNA or engineered RNA, classifiable in class 435, subclass 375

IV. Claims 1 and 6, drawn to a method for delivering an siRNA or engineered RNA to a cell wherein the method comprises conjugating the delivery peptide VP22 to an siRNA or engineered RNA, classifiable in class 435, subclass 375

V. Claims 1 and 7, drawn to a method for delivering an siRNA or engineered RNA to a cell wherein the method comprises conjugating the delivery peptide MPG to an siRNA or engineered RNA, classifiable in class 435, subclass 375

VI. Claims 8 and 9, drawn to a method for delivering a siRNA to a cell comprising forming a mixture of siRNA with at a dendrimer, classifiable in class 435,

subclass 6. This group is further subject to restriction to a single sequence per below.

VII. Claims 10 and 11, drawn to a kit for conjugating a delivery peptide to a siRNA classifiable in class 435, subclass 6. This group is subject to an additional restriction as per below.

VIII. Claims 12 and 13, drawn to a kit for preparing a siRNA delivery mixture comprising a dendrimer PAMAM, classifiable in class 435, subclass 6.

IX. Claim 14, drawn to a siRNA delivery mixture, classifiable in class 536, subclass 24.5.

X. Claims 15 and 16, drawn to a siRNA or engineered RNA precursor conjugated to a delivery peptide, classifiable in class 435, subclass 6. This group is subject to an additional restriction as per below.

The inventions are distinct, each from the other because of the following reasons:

The methods of groups I, II, III, IV and V are all unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different methods are not disclosed as useful together because they have materially different modes of operation with different effects. For example, the methods of delivering a siRNA or engineered RNA wherein the siRNA or engineered RNA that is conjugated to delivery peptides, such as Tat, MTS, MPG, hox, VP22 and a peptide having SEQ ID NO: 12, are not disclosed as capable of use together because the delivery peptides have

different sequences and materially different modes of translocation of molecules across the cell membrane. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

The methods of groups I-V and the method of group VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different methods are not disclosed as useful together because they have materially different modes of operation with different effects. For example, the delivery of a siRNA or engineered RNA that is conjugated to a delivery peptide is materially different than delivering a siRNA or engineered RNA conjugated to a dendrimer because the delivery peptides and the dendrimer are different molecules and have different functions, effects and modes of operation and further not disclosed as useful together. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

The methods of groups I-V and the method of group VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as useful together because they have materially different modes of operation with different effects. For example, the methods of delivering a siRNA molecule or engineered RNA conjugated to a delivery peptide is

materially different than the invention of group VII, which is drawn to a kit for conjugating a delivery peptide to a siRNA, and further comprises reagents and elements not necessarily involved in the inventions of groups I-V. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

The methods of groups I-V and the method of group VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as useful together because they have materially different modes of operation with different effects. For example, the method of delivery of a siRNA or engineered RNA conjugated to delivery peptide is materially different than the invention of group VIII, which is drawn to a kit for preparing a siRNA delivery mixture, and further comprises reagents and elements not necessarily involved in the inventions of groups I-V. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

The methods of groups I-V and the method of group IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as useful together because they have materially different modes of operation with different effects. For example, the method of delivery of a siRNA or engineered RNA conjugated to delivery peptide is materially

different than the invention of group IX, which is drawn to a siRNA delivery mixture comprising a dendrimer and is not disclosed as useful in the inventions of groups I-V. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of groups I-V and group X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method for delivering an siRNA or engineered RNA precursor to a cell can be practiced using an entirely different compound. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

The inventions of group VI and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as useful together because they have materially different modes of operation with different effects. For example, the method of delivery of a siRNA or engineered RNA conjugated to a dendrimer is materially different than the invention of group VII, which is drawn to a kit for conjugating a delivery peptide to a siRNA,

and further comprises reagents and elements not necessarily involved in the inventions of group VI. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

The inventions of group VI and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as useful together because they have materially different modes of operation with different effects. For example, the method of delivery of a siRNA or engineered RNA conjugated to a dendrimer is materially different than the invention of group VIII, which is drawn to a kit for preparing a siRNA delivery mixture comprising a dendrimer, and further comprises reagents and elements not necessarily involved in the inventions of group VI. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of group VI and group IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method for delivering an siRNA or engineered RNA precursor to a cell can be practiced using an entirely different compound, such as an siRNA conjugated to a delivery peptide. Furthermore restriction is proper because the

subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

The inventions of group VI and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as useful together because they have materially different modes of operation with different effects. For example, the invention of group VI is drawn to a method of delivering a siRNA or engineered RNA conjugated to a dendrimer and the invention of group X is drawn to a siRNA conjugated to a delivery peptide are not disclosed as useful together. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

The inventions of group VII and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as useful together because they have materially different modes of operation with different effects. For example, the invention of group VII is drawn to a kit for conjugating a delivery peptide to a siRNA and the invention of group VIII is drawn to a kit for conjugating a siRNA to a dendrimer, which are not disclosed as capable of use together. Furthermore restriction is proper because the subject matter is divergent

and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

The inventions of group VII and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as useful together because they have materially different modes of operation with different effects. For example, the invention of group VII is drawn to a kit for conjugating a delivery peptide to a siRNA and the invention of group IX is drawn to a delivery mixture comprising a dendrimer, which are not disclosed as capable of use together. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

The inventions of group VII and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as useful together because they have materially different modes of operation with different effects. For example, the invention of group VII is drawn to a kit for conjugating a delivery peptide to a siRNA and the invention of group X is drawn to a siRNA or engineered RNA precursor conjugated to a delivery peptide, which are not disclosed as capable of use together. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily

reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of group VIII and group IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method for delivering an siRNA or engineered RNA precursor to a cell can be practiced using an entirely different compound, such as an siRNA conjugated to a delivery peptide. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

The inventions of group VIII and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as useful together because they have materially different modes of operation with different effects. For example, the invention of group VIII is drawn to a kit for conjugating a dendrimer to a siRNA and the invention of group X is drawn to a siRNA or engineered siRNA conjugated to a delivery peptide, which are not disclosed as capable of use together. Furthermore restriction is proper because the subject matter

is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

The inventions of group IX and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as useful together because they have materially different modes of operation with different effects. For example, the invention of group IX is drawn to a siRNA delivery mixture comprising a dendrimer and the invention of group X is drawn to a siRNA or an engineered RNA precursor conjugated to a delivery peptide, which are not disclosed as capable of use together. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Furthermore, should applicants elect to prosecute group VII or group X, these groups are subject to a further restriction as follows. Claims 11 and 16 are subject to an additional restriction since it is not considered to be a proper genus/Markush. See MPEP 803.02 –

PRACTICE RE MARKUSH-TYPE CLAIMS – if the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claims on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require restriction. Since the decisions in In re Weber, 580 F.2d 455, 198 USPQ 300 (CCPA 1980); and In re Haas, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. In re Harnish, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structure feature disclosed as being essential to that utility.

Claim 11 and 16 specifically claims delivery peptides selected from the group consisting of Tat, homeobox, MTS, MPG and VP22. Although the delivery peptides claimed each can be conjugated to a siRNA or engineered RNA precursor, the instant delivery peptides are considered to be unrelated, since each delivery peptide claimed is structurally and functionally independent and distinct for the following reasons: each delivery peptide has a unique nucleotide sequence and each delivery peptide has a different mode of operation, function or effect. As such the Markush/genus of delivery peptides in claims 11 and 16 are not considered to constitute a proper genus, and are therefore subject to restriction. Furthermore, a search of more than one (1) of the delivery peptides claimed in claims 11 and 16 presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of

more than one (1) of the claimed delivery peptides. In view of the foregoing, one (1) delivery peptide is considered to be a reasonable number of peptides for examination. Accordingly, applicants are required to elect a total of one (1) delivery peptide from claims 11 and 16. Note that this is not a species election.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to

retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly Chong whose telephone number is 571-272-3111. The examiner can normally be reached Monday thru Friday between 7-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached at 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system

provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see http://pair-direct.uspto.gov.

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Kimberly Chong
Examiner
Art Unit 1635

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1635